

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA  
BEAUFORT DIVISION

The United States of America ex rel. Scarlett ) C/A No.: 9:14-cv-0230-RMG  
Lutz, Kayla Webster, Dr. Michael Mayes, ) (Consolidated with 9:11-cv-1593-RMG  
and Chris Reidel, ) and 9:15-cv-2485-RMG)  
 )  
 Plaintiffs, )  
 )  
 v. )  
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 Berkeley Heartlab, Inc., et al., )  
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 Defendants. )  
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**DENT AND JOHNSON'S REPLY IN SUPPORT OF THEIR MOTION FOR  
JUDGMENT AS A MATTER OF LAW, OR IN THE ALTERNATIVE, A NEW TRIAL**

Defendants Dent and Johnson (collectively "Defendants") submit this Reply to respond to numerous issues raised in the government's Opposition to Defendants' Motions for Judgment as a Matter of Law and/or New Trial ("Opposition") and incorporate by reference, as if set forth at length, Defendant Latonya Mallory's Reply to the United States' Opposition to Defendants' Motions for Judgments as a Matter of Law and/or New Trial (Docket Entry # 891), to the extent it is not inconsistent with the arguments set forth herein.

## **INTRODUCTION AND SUMMARY**

Justice Oliver Wendell Holmes wrote that “Men must turn square corners when they deal with the Government.” *See Rock Island A. & L.R. Co. v. United States*, 254 U.S. 141, 143 (1920). “That advice cuts both ways: those who deal with the government have a right to expect fair treatment in return.” *In re Keeper of Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 26 (1st Cir. 2003). Nowhere is the government’s obligation to deal fairly with constituents more critical than it is under the FCA and AKS. Those laws are intended to fight fraud and give the government far more power than it has in most other contexts. With that power comes commensurate responsibility to use it properly and honor citizens’ rights. The government has fallen short here, and it is not enough merely to say that Defendants had their day in court and that the jury has spoken. The court must guard the essential rights that these statutes implicate. Only the court can look at the big picture and determine when the government has misused them. While nobody has a right to a perfect trial, the court must decide whether, all things considered, Defendants received a fair one and whether Defendants’ conduct warrants the punitive, confiscatory remedies the government seeks.

The government asks this Court to consider Defendants’ arguments for judgment as a matter of law and for a new trial separately, in isolation. Viewed this way, no one thing that Defendants complain about might seem critically important. Ultimately, however, the Court must decide whether these powerful statutes were properly and fairly applied and that Defendants got the fair trial that citizens should have before the government can take everything that they own.

The United States tried this case on the theory that Defendants’ failure to heed unofficial opinions establishes a knowing and willful violation of the law. The Supreme Court has said that rigorous enforcement of materiality and scienter mitigates the FCA’s harshness. This Court determined pre-trial that materiality is satisfied when FCA liability is premised on a violation of the AKS. This leaves scienter as the last check against the confiscatory application of the law. Merely failing to heed red flags is not the same as a knowing and willful violation of the law.

Viewing the evidence in the light most favorable to the government, Defendants followed long-standing business practices that were ubiquitous in their industry and that multiple attorneys endorsed. Even after they knew that the government was investigating their practices, nobody advised them to stop. In fact, they understood that HDL’s healthcare attorneys – Ropes & Gray, the same firm that advised Berkeley Heartlab in 2005 (when Dent and Johnson were employed there) that P&H fees were legal – was working with the government to determine in what form the practices could continue. When the government finally issued its Special Fraud Alert on June 25, 2014, its analysis relied not upon the plain text of the law, but on decades-old administrative interpretations of the AKS. Those interpretations had did not even addressed payment of P&H fees or payment of sales commissions and, by their own terms, could not be relied upon by third parties. The Special Fraud Alert relied upon arcane interpretations of complex Medicare reimbursement policies, and did not unequivocally pronounce P&H fees impermissible. Nevertheless, that the government had finally taken a position on P&H fees was enough for Defendants; they never again sold laboratory tests that included P&H reimbursement. Defendants followed universally accepted practices and were never advised to stop. They failed to foresee that the Justice Department would retroactively interpret the AKS to outlaw P&H fees and sales commissions and determine that the Defendants’ business practices had crossed an invisible line. Defendants’ conduct does not warrant the Draconian punishment imposed.

Additionally, Defendants never made claims. Rather, the United States argues that they “caused” false claims, even though it did not prove which, if any, claims they caused. Further, the government suffered no harm from any claims, except by virtue of the legal fiction that it should not pay anything for claims that an AKS violation “taints.” The government has already received from HDL and Singulex more than complete satisfaction of any damage that it could have sustained by virtue of Defendants’ actions. Finally, Defendants benefitted only marginally from the claims that the jury found violated the FCA. Despite all this, the United States intends to take everything they own or ever will own.

For these reasons, Defendants did not receive a fair trial. The United States sought and received permission to tell the jury how much money Defendants made, for the unabashed purpose of arguing that anyone making that much money should know that he is breaking the law. The government sought and received permission to hide from the jury the real effect of a verdict, so the jury was unaware that it could be multiplied many times over rather than be a significant “slap on the wrist” as it undoubtedly intended. The United States exploited these advantages and found an eager audience. The United States abused discovery, to the Defendants’ great detriment. The circumstances *taken together* warrant a new trial.

Defendants should be given judgment as a matter of law or, in the alternative, a new trial.

## **ARGUMENTS**

### **I. The Jury Foreman’s Facebook Posts Require a New Trial**

This Court should decline the United States’ invitation to examine the jury foreman’s Facebook posts in isolation. Rather, it should examine what the juror’s conduct reflects about the trial as a whole. The government consistently brought up Defendants’ wealth and insinuated that they personally profited from kickbacks to the tune of tens of millions of dollars. Of the \$17,069,526 value of the claims in the verdict, Defendants received a small fraction of what the government paid. This is because BlueWave (which the jury exonerated) received commissions based on a percentage of HDL’s and Singulex’s revenues, from which it then had to pay its expenses including income taxes, sales contractors’ commissions, and operating expenses before profits trickled down to its owners. Also, the government commingled BlueWave’s and Defendants’ revenues from *non*-Medicare sales with “false claims.” The United States repeatedly told the jury that Dent and Johnson made more than fifty million dollars each, though only a tiny fraction of this was even arguably attributable to false claims. The government constantly used terms like “blood money” to impugn Defendants. The government defends its use of that term by arguing that it was accurate since Defendants “paid money (P&H fees) ‘to get the blood to their facility.’” (See Docket Entry No. 887, at 23). However, “blood money” has very well-known

definitions, which are far more inflammatory, including a fee paid to a hired murderer; compensation paid to the next of kin of a slain person; money obtained ruthlessly and at a cost of suffering to others; or money paid to an informer in order to cause somebody to be arrested, convicted, or especially executed. *See* <http://www.dictionary.com/browse/blood-money?s=t> (accessed March 18, 2018). The government's primary trial strategy was to highlight Defendants' success and appeal to bias against the wealthy. They struck gold with the jury foreman, who embraced that theme and could not restrain himself: "I don't know why it's so funny when rich people fall down; . . . there were at least 100 people, in that room, who enthusiastically agreed." (January 17). The prejudicial effect of those tactics is unmistakable.

## **II. The Court Should Rule in Defendants' Favor on Numerous Crucial Legal Issues**

### **A. The Court Should Not Apply "One Purpose Rule"**

The government contends that it should get the benefit of the "one purpose" test. Its construction of the AKS criminalizes conduct the primary purpose of which is legitimate. Given the punitive nature of the AKS remedies available, the government's request to apply the "one purpose" rule extends AKS' the reach beyond its intended breadth. The primary purpose of the P&H Fees was permissible: to reimburse physicians for expenses at fair market value and pass Medicare payments made to laboratories for process and handling portion of the blood testing process to the party that actually did the work. The only purpose of sales commissions was to compete salespeople for their work. The government should not be permitted to bring about the financial ruin of two businessmen when the purpose of the fees was to reimburse physicians at market value and the purpose of commissions was to compensate sales representatives for their services at fair market value. In fact, the overwhelming testimony was that no purpose of the P&H fees and commissions was to unlawfully induce referrals. (TT, at 1601).

### **B. Plaintiff Has Not Shown Materiality**

Although the government writes it off as a technicality, the Supreme Court has held that "materiality" is a demanding limitation on the government. *See Universal Health Serv's, Inc. v.*

*United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016). The Court declined to instruct the jury on this element. The Defendant has previously argued this point in full, but it cannot be gainsaid that the Supreme Court views the government's obligation to prove materiality as an essential safeguard against the overreaching application of the confiscatory FCA penalties.

**C. The AKS As Applied Is Unconstitutionally Vague**

The government argues that the AKS is not unconstitutionally vague and claims that Defendants have not identified evidence of vagueness. The government's statements regarding the AKS, related regulations and guidance to the P&H Fees admit the vagueness surrounding this issue. In Mallory Exhibit 123, the lead attorney for the Department of Justice in this case, Elizabeth Strawn, acknowledged the deficiency in the government's notice: "Elizabeth told R&G that they have never had a situation like this in the past where an advisory opinion was written in the middle of an investigation and admitted that these are typically written when there are areas that are vague or not spoken that need to be clarified." *Id.* (emphasis added). The government's own acknowledgement establishes that the statute, regulations and guidance as applied are unconstitutionally vague. That other courts have found the AKS constitutional is of no moment; this is the first time that the issue of P&H fees and commissions paid at FMV has been contested.

**D. Defendants Did Not Waive Safe Harbor Defense**

The issue of the AKS safe harbor, 42 C.F.R. § 952.1001(d), was tried by implied consent, and not waived. Fed. R. Civ. P. 15(b)(2) ("When an issue not raised by the pleadings is tried by the parties' express or implied consent, it must be treated in all respects as if raised in the pleadings. A party may move—at any time, even after judgment—to amend the pleadings to conform them to the evidence and to raise an unpleaded issue. But failure to amend does not affect the result of the trial of that issue.").<sup>1</sup> Both parties offered AKS safe harbor evidence into the record, so there was no prejudice to the government. (TT, at 79, 679, 708, 735, 825, 883, 1285, 1296, 1300, 1468, 1603, 1832, 2358, 2553). Defense counsel argued the AKS safe harbor.

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<sup>1</sup> To the extent the Court deems it necessary, Defendants move to amend their answer to conform to the trial evidence, to include the subject AKS safe harbor affirmative defense.

(TT, at 2687, 2694-5). *McLeod v. Stevens*, 617 F.2d 1038, 1040 (4th Cir. 1980) (“The admission of evidence without objection concerning an issue that is the subject of amendment is an indicium of implied consent.”). The P&H fee and commission agreements met the safe harbor.

#### **E. The Payment of Commissions Does Not Violate the AKS**

The case that the government cites for its argument that the AKS prohibits commissions, *United States v. Miles*, 360 F.3d 472 (5th Cir. 2004), found no AKS violation under similar facts:

The appellants assert that they cannot have violated this statute because Premier never actually referred anyone to APRO, but simply engaged in advertising activities on behalf of APRO. . . . Based on the evidence adduced at trial, we agree with the appellants. In this case, Premier supplied promotional materials to Houston-area doctors describing APRO’s home health care services. . . . There was no evidence that Premier had any authority to act on behalf of a physician in selecting the particular home health care provider.

*See id.* at 479-80. Likewise, commissions to Defendants did not violate the AKS, because they were not paid to make referrals, but to market services. Numerous witnesses confirmed that Defendants were not decision-makers for referrals;<sup>2</sup> had no inside positions of influence;<sup>3</sup> and did not recommend HDL to patients (and were not in position to do so).<sup>4</sup> Also, the jury properly exonerated BlueWave, eliminating any possible liability for claims regarding commissions. No commissions could have been intended to induce referrals, but to compensate for proper work.

#### **F. The Court Improperly Excluded Certain Expert Testimony**

For the reasons set forth in Defendants’ prior filings, the Court improperly excluded opinion testimony by various expert witnesses, prejudicing Defendants.

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<sup>2</sup> See *Miles*, *supra*.

<sup>3</sup> See *U.S. v. Shoemaker*, 746 F.3d 614 (5<sup>th</sup> Cir. 2014) (may be liability if *hospital official* received money to use his inside influence to steer procurement decisions, though he had no actual authority as decision-maker.)

<sup>4</sup> See *U.S. v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1056-57 (C.D. Cal. 2016) (payments to speakers did not violate AKS: “We think the term ‘recommendation’ was only intended to encompass recommendations that pertain to specific patients. There is no evidence that Celgene’s speakers made recommendations pertaining to specific patients.”).

### **III. No Reasonable Jury Could Find in the Government's Favor**

#### **A. Defendants Did Not Knowingly and Willfully Violate the AKS**

##### **1. The Government Failed to Satisfy the "Remuneration" Requirement**

The government has not carried its heavy burden of showing that Defendants offered, paid, solicited or received remuneration to induce a referral. The P&H fees were not remuneration, as: (a) Defendants did not pay them and (b) they represented fair market value for work performed. There can be no illegal remuneration as to the P&H fees and commissions unless the government proves that the amounts paid exceed fair market value. The Special Fraud Alert emphasizes the importance of proof that compensation exceeds fair market value. (See Mallory Ex. 104). In light of the government's nuclear remedy, it cannot show a kickback without proving that physicians were paid excessive amounts to induce referrals.

The government has not shown that the P&H fees were above fair market value reimbursement. In fact, HDL's P&H fee was the lowest per tube in the entire industry. (TT, at 434:12-15). The per-click compensation that the government contends is *per se* illegal, is the same method by which Medicare reimburses the \$3.00 draw fee. That the government did not claim that the per click reimbursements of the \$3.00 venipuncture fee violated the law underscores that P&H fees paid at or below fair market value do not violate the law either. All Medicare fees paid to a physician are "per click" and based upon calculation per patient encounter, as that is the only fair way to do so for a fee for service. P&H fees are no different.

Even if reimbursement at market value could be remuneration and an inducement, absent the inference created by an above-market-value payment the intent to induce would have to be shown on a case-by-case basis: i.e., the government must show that each instance of alleged remuneration actually led to a specific false claim. The government offered no such evidence that any P&H fee induced any particular claim. There is no evidence of any double payments. Both Dr. Alam and Dr. Hollins testified that P&H fees had no impact on their decision to use HDL and Singulex lab testing, and that they continued to do so even after P&H fees ended.

## **2. The Government Failed to Satisfy the Inducement Requirement**

The government failed to present evidence that Defendants induced anyone to refer a specific patient for a specific test, relying instead on vague generalities and rank speculation.

## **3. The Government Cannot Satisfy the *Scienter* Requirement**

Consistent with its campaign to impose ruinous punishment on Defendants without proper safeguards, the government maintains that its claims require proof only by a preponderance of evidence, even though the penalty is of criminal magnitude. A lesser *scienter* standard runs afoul of the intent of the AKS and the FCA and disregards the need for the government and the courts to protect citizens from arbitrary imposition of ruinous punitive damages and penalties for a supposed violation of an invisible law.

The Supreme Court has held that it would check potential abuses under the FCA and that “concerns about fair notice and open-ended liability ‘can be effectively addressed through strict enforcement of the Act’s materiality and scienter requirements.’” *See Universal Health Servs., Inc. v. United States, ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016) (citation omitted). This Court deemed that the government established materiality as a matter of law. As a result, the *scienter* requirement was the only remaining check on the FCA’s draconian penalties. Consequently, the only reasonable *scienter* is intent to break the law. The government could never prove such *scienter* because the law was not sufficiently clear to place a reasonable person on notice of whether he was violating it. Given the magnitude of penalties, it should not be enough for the government to prove that Defendants may have missed “red flags” or engaged in a risky practice.

Congress intentionally created an exceptionally high *scienter* standard for the FCA, and an even higher one for the AKS, to prevent government overreaching. The term “knowingly” may only “require[] proof of knowledge of the facts that constitute the offense.” *See Ratzlaf v. United States*, 510 U.S. 135, 137; *Bryan v. United States*, 524 U.S. 184, 193 (1998); *Dixon v. United States*, 548 U.S. 1 (2006). However, “willfully” requires proof that Defendants knew “that his conduct was unlawful,” that he was acting “with a bad purpose,” or that he was acting “with evil intent without justifiable excuse.” *See Bryan*, 524 U.S. at 192-193. As the Supreme

Court confirmed, “concerns” about the FCA “can be effectively addressed through strict enforcement of the Act’s materiality and scienter requirements.” *Escobar*, 136 S. Ct. at 2002.

The government has not shown “knowing” or “willful” acts. Defendants followed attorneys’ advice and industry standards when there was substantial uncertainty. The government cannot show that Defendants knew that they were committing illegal acts, because they did not do so. The totality of the circumstances led Defendants to believe that they were not violating the law, including the long-standing industry practice of paying P&H fees, which long predated BlueWave. Additionally, various legal opinions and reviews confirmed that the conduct of HDL, Singulex and Defendants did not violate any federal law. Ropes & Gray — the same firm that would later advise HDL — provided an opinion to BHL to that effect in 2005. BW Ex. 493. On April 27, 2012, former longtime Department of Justice lawyer, Michael Ruggio, provided an opinion to HDL, stating in part that “Based on this careful study this arms-length fixed-in-advance fair market value fee will fall into the safe harbor exceptions under Anti-Kickback statutes and Civil False Claims Act to alleviate any issue in that regard.” Mallory Ex. 7. Numerous lawyers and consultants reviewed the sales and P&H agreements and did not express any concern that they were illegal. These included Ballard Spahr representing Singulex; Navigant Consulting (which reviewed the P&H Fee and Commission contracts for Singulex), and the Saranac Group (which did a compliance review for HDL). No attorney ever advised HDL or Singulex to stop paying P&H fees or to stop paying sales commissions. Whenever a question was raised about any business practice, Defendants dutifully referred them to HDL to be reviewed by its healthcare attorneys. The government cannot show that the law was so clear that Defendants acted knowingly and willfully. As stated above, even lead Department of Justice attorney Strawn admitted the ambiguity involving P&H fees and the AKS.

The government relies on the June 25, 2014, Special Fraud Alert for its contention that Defendants knew that their actions violated the AKS. Mallory Ex. 7. Even after the SFA, there was confusion regarding the legality of P&H fees; attorneys from Ropes & Gray initially believed that the SFA strengthened that P&H fees were legal because OIG had for the first time

acknowledged that the \$3 venipuncture fee was separate from the process and handing function. BW Ex. 123. Defendants questioned this position and ceased any involvement with P&H fees.

The government's position relies entirely upon certain "guidance" from the Office of the Inspector General construing the AKS. However, those advisory opinions state that they may not be relied upon by anyone other than the person or entity who requested the opinion. *See* TT at 1364; 42 C.F.R. § 1008.53; *accord* 42 C.F.R. § 1008.55(b). Moreover, the Attorney General has restricted the use of guidance documents. *See* Memorandum: Prohibition on the Use of Improper Guidance Documents (Nov. 16, 2017 U.S. Atty. Gen.) ("[G]uidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch.").<sup>5</sup> The government may not rely upon OIG guidance to impute knowledge to Defendants of prohibited conduct. The burden and cost of ambiguity should be on the government rather than on the regulated entity. *See, e.g., Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1328-20 (D.C. Cir. 1995); *United States v. Trident Seafoods Corp.*, 60 F.3d 556, 559 (9<sup>th</sup> Cir. 1995). Further, liability under the FCA cannot be imposed where the defendant "merely took advantage of a disputed legal issue." *Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1478-79 (9<sup>th</sup> Cir. 1996); *see also U.S. ex. Rel. Donegan v. Anesthesia Assocs. Of Kansas City, PC*, 833 F.3d 874, 879 (8<sup>th</sup> Cir. 2016) (reasonable interpretation of ambiguous provision was "regulatory noncompliance, not an FCA claim"); *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7<sup>th</sup> Cir. 1999) (reasoning that "faulty calculations," "flawed reasoning," "imprecise statements," or "differences in interpretation" are not "false"). *A fortiori*, a FCA violation premised on an AKS violation must be based upon more than a defendant guessing wrong about where the government draws its invisible line of prohibition.

## **B. Defendants Did Not Cause Claims for Medically Unnecessary Services**

The government presented no evidence that any physician ordered a test that did not benefit a patient; rather, testimony showed that tests were both medically necessary and

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<sup>5</sup> Available at <https://www.justice.gov/opa/press-release/file/1012271/download>.

prevented future costly cardiac events. (TT, at 792:12-793:7; 1901:21-1902:3; 2188:20-2189:22; 2255:20-2256:2). While the government's expert, Dr. Jeffery Trost, contended that tests were unnecessary for *routine* patients, the government presented no evidence that tests were used for routine patients or that non-cardiologist physicians would have no use for the tests. The only physicians who testified regarding use of the tests stated that their patient populations included mostly patients at moderate to high risk. (TT, at 2193:4-25; 2201:3-8; 2289:4-7).

The government's position that Defendants knowingly caused the submission of medically unnecessary tests for *routine patient populations* through the use of test panels which went beyond a traditional lipid panel is not supported by any evidence. First, the only physicians who testified regarding their use of the tests indicated that their patient populations consisted of moderate to high risk patients. The government infers that the tests were ordered on patients with no risk factors, with no supporting record evidence. Second, Defendants' expert Dr. Fishberg testified that each test offering was medically necessary, if a physician so determined. (TT, at 1958:7-25). As Defendants and BlueWave sales representatives repeatedly testified, only physicians could determine which tests to order. The government points to relator Dr. Mayes' testimony that members of his practice stopped ordering tests once P&H fees were no longer paid. (See Docket Entry No. 887, at 24). Dr. Mayes' financial self-interest aside, the evidence shows that his partners reduced orders before the end of P&H fees. (See BW 254, TT MAYES).

### **C. The Jury Could Not Find That the United States Proved Damages**

For the reasons set forth in Defendants' Memorandum in Opposition to the United States' Motion for Entry of Judgment ("Rule 54 Memorandum"), the government has not presented sufficient evidence of recoverable damages under the FCA. (See Docket Entry # 888).

## **IV. Defendants Have Suffered a Miscarriage of Justice**

### **A. Evidentiary Errors Resulted in a Miscarriage of Justice**

The United States focused on Defendants' "love of money," stating at the very beginning of trial that "it's about what the defendants were willing to do for the love of money." (See TT, at

31:20-21). The government continued this overarching theme by prejudicially pointing to Defendants' prior financial success at another lab where "they were making hundreds of thousands of dollars a year, but they wanted more." (See TT, at 32:5-6). These statements were made within the first minute of trial. While focusing on the "love of money," the government misused evidence of Defendants' wealth by repeatedly stating that each Defendant made over \$50 million (neglecting to mention that only a portion came from government payors).

As argued in Defendants' Memorandum in Support of Motions for Judgment as a Matter of Law and/or New Trial (Docket Entry # 880-1), these and other evidentiary issues have, individually and in combination, caused a miscarriage of justice.

**B. Errors in the Jury Instructions Resulted in a Miscarriage of Justice**

For the reasons set forth in Defendants' Memorandum in Support of Motions for Judgment as a Matter of Law and/or New Trial (Docket Entry # 880-1), the jury instructions materially misled the jury and caused a verdict that is not supported by the law and is unjust.

**C. The Jury's Verdict Was Internally Inconsistent**

First, Defendants have not waived their argument as to the inconsistent verdict by not objecting before the Court discharged the jury. After the verdict was published and the jury polled, the jury was directed to the jury room. The judge stated he was going to thank the jury, not that the judge was going to discharge or dismiss the jury. As soon as the judge returned from thanking the jury, defendants raised their objection to the inconsistent verdict under Rule 49. There was no indication in the record that the jury had been discharged at the time of the objection to the inconsistency. (TT, at 2972-74). The government made no contemporaneous objection so that corrective action could be taken by the court, if needed, and thus acquiesced in the timeliness of Defendants' instant motions. Defendants were given no opportunity to object prior to a so-called discharge.<sup>6</sup> See *Riddle v. Tex-Fin, Inc.*, 719 F. Supp. 2d 742, 752-53

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<sup>6</sup> It is standard for a court to allow a party to object prior to discharge. See *Stancill v. McKenzie Tank Lines, Inc.*, 497 F.2d 529 (5th Cir. 1974) (judge asked for objections in front of jury and conferred with counsel at bench concerning objections); *Ludwig v. Marion Laboratories, Inc.*, 465 F.2d 114, 118 (8th Cir.1972) (immediately after jury's findings, off-record discussion

(S.D. Tex. 2010) ("[F]ailure to object to inconsistent answers when the jury returns its verdict does not waive the right to raise the issue in a motion for a new trial because 'the judge has no authority to enter judgment based upon those answers.'") (citation omitted); *accord Johnson v. ABLT Trucking Co.*, 412 F.3d 1138, 1141 (10th Cir. 2005) ("When a jury returns a special verdict ... a party is not required to object to inconsistencies in the verdict before the jury is discharged in order to preserve the issue."); 9B Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 2510 (3d ed. 2008) ("[A] new trial under Rule 59(a) ordinarily is the proper pathway for the trial judge to follow and may be the required course."). The court can reconvene the jury to correct any inconsistency. *Los Angeles Nut House v. Holiday Hardware Corp.*, 825 F.2d 1351 (9th Cir. 1987). Furthermore, prior to judgment, at the March 21, 2018 hearing, Defendants requested the Court to recall the jury to address the verdict's inconsistency. Upon information and belief, the Court indicated that there was no waiver of that objection.

Second, Defendants were BlueWave's owners, officers, managers and agents. Every action they took to market tests was on its behalf. They are so interconnected and intertwined with BlueWave that it is inconceivable that Defendants could be found liable and BlueWave not be. (TT, at 1125-82). The Sales Agreements, which Defendants signed on BlueWave's behalf, contained P&H fee provisions, waiver of co-pay provisions, and commission provisions that formed the basis of the government's case. BlueWave received sales commissions for tests, distributed sales commissions, and sold the tests for the laboratories. The jury instructions stated that "a corporation is liable for a conspiracy committed by its officers, employees, or agents if the conspiracy is committed at least in part for the benefit of the corporation." (TT, at 2960). The instructions allowed the imputation to BlueWave of its contactors' alleged unlawful acts. There is no way to harmonize the jury's verdict of liability for Defendants and absolution of BlueWave.

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between court and counsel); *Tennessee Consolidated Coal Co. v. UMW*, 416 F.2d 1192, 1200-01 (6th Cir. 1969) (court inquired whether counsel had anything to raise before excusing jury); *Kirkendoll v. Neustrom*, 379 F.2d 694, 699 (10th Cir. 1967) (court asked if reason not to discharge jury and counsel answered in negative). Defendant's Seventh Amendment right to a jury trial requires that the Court either harmonize the verdict or grant a new trial.

**D. The Government's Discovery Abuse Resulted in a Miscarriage of Justice**

The United States focuses on the fact that most of the *volume* of documents presented were made prior to the June 2, 2017 discovery cutoff. This response omits the vital importance of the alleged 2% of documents that it produced only *after* the close of discovery, *after* the Court ruled on Daubert motions in its favor, and *after* it secured a strategic advantage by failing to disclose its rationale for the theory that all P&H payment functions are subsumed by the E/M code payment to physicians. The United States designated that rationale as privileged “deliberative process,” but relented after motions to compel. The coding rationale goes to the heart of Defendants’ arguments that it was unclear prior to the SFA whether P&H fees were remuneration or inducement under the AKS. The United States’ debate of that issue internally from 2012-14 demonstrates ambiguity, which excluded defense expert Daniel Mulholland correctly addressed. The contrary viewpoint of CPT coding expert, Dennis Padgett regarding the E/M code was similarly withheld from Defendants until after discovery was closed and depositions were completed. This disagreement eroded the government’s theory that Defendants could have had *scienter* when there was such a stark difference of opinion.

**V. Dent and Johnson Are Entitled to the Requested Setoffs (Opposition § V)**

The government settled with HDL for nearly \$100 million and Singulex for \$1,500,000, and also with other sources. These settlements *fully* offset any damages that Dent and Johnson could have caused. The government argues that Defendants are not entitled to a full setoff because the settled claims include additional claims, such as offering kickbacks in “speaker programs; advisory boards; consulting arrangements” and for paying claims that were not properly coded. The government could have pursued claims for those damages, if it believed that they had merit, but such claims were dismissed for abandonment. (See Docket Entry No. 693).

The government limits Defendants’ offset to 12% of the settlement for HDL and 10% for Singulex. The settlements do not designate how the government intended to allocate those settlements and whether any portion of those settlements should be attributed to the 90% of

claims that the jury determined were not false. There is no logic in the government's invitation to allocate nearly all of nearly \$100 million settlements to claims the jury found meritless.

The government argues that Defendants are only entitled to an offset on the amount of cash that the government actually received. Selectively citing the words "previously received" from two cases that did not even analyze the issue, the government ignores that: (a) it received present value in the full amount of the settlements; and (b) Defendants should *also* be entitled to an offset for any amounts the government receives in the future. The settlements with HDL and Singulex are just that: settlements. They are assets. They represent the reduction of contingent claims to an agreed value in an enforceable agreement. HDL and Singulex agreed not to contest the existence or amounts of those claims. Moreover, as to the payable portions of the HDL settlement, the government is the largest HDL creditor, so it will receive most of what the Trustee brings to the estate. The United States makes no legitimate argument shielding "unpaid" portion of a settlement from setoff. The government also argues that Defendants should not get credit for most of the HDL settlement, wherein the government received non-cash value for reducing its claim by that amount. The HDL estate waived the attorney-client privilege as to certain documents demanded by the government in exchange for the release of \$53,500,000.02 in claims against the estate; concessions that the government deemed extraordinarily valuable. Judgments may be set off by settlements for non-cash consideration. *See Methyl Tertiary Butyl Ether (MTBE Prod. Liab. Litig.*, 578 F. Supp. 2d 519 (S.D.N.Y 2008). The government considered these documents so important that it would forego a vast sum of money to obtain them. Defendants are entitled to a dollar-for-dollar offset in the full amount of the proof of claim that the government waived in consideration of receiving potentially helpful HDL documents.

## **VI. The Government May Not Pursue Equitable Remedies (Opposition §§ VI.A and B)**

For the reasons set forth in Defendants' Rule 54 Memorandum, the government is not entitled to continue pursuing equitable remedies. (*See* Docket Entry # 888).

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Respectfully submitted,

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